



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

The Arthritis Foundation - Food and Drug Administration Accelerating Osteoarthritis Clinical Trials Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop.

SUMMARY: Osteoarthritis is the most common form of arthritis, and occurs when the cartilage that cushions the bones of the joint break down and the bones begin to rub together. This can cause pain, swelling, and loss of motion of the joint. The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in co-sponsorship with the Arthritis Foundation is announcing a workshop entitled, "Accelerating OA Clinical Trials Workshop". The purpose of the workshop is to discuss recommendations from the international Arthritis Foundation Accelerating Osteoarthritis Clinical Trial workgroup and identify next steps in forging new approaches to osteoarthritis clinical trials that may improve the likelihood of successful conduct and outcomes of these trials and lead to the development of safe and effective treatments for osteoarthritis.

DATES: The workshop will be held on February 24, 2016, from 8 a.m. to 5:30 p.m., and February 25, 2016, from 8 a.m. to 2 p.m.

ADDRESSES: The workshop will be held at the Atlanta Airport Hilton, 1031 Virginia Ave., Atlanta, GA 30354.

FOR FURTHER INFORMATION CONTACT: Sarah Yim, Office of New Drugs, Center for Drug Evaluation and Research, email: sarah.yim@fda.hhs.gov; Amanda Niskar, Arthritis

Foundation, Inc., 1330 West Peachtree St., Atlanta, GA 30309, 404-964-7545, FAX: 404-965-7807, email: aniskar@arthritis.org; or Becky Bosworth, Arthritis Foundation, Inc., 1330 West Peachtree St., Atlanta, GA 30309, 404-965-7673, email: bbosworth@arthritis.org.

SUPPLEMENTARY INFORMATION:

I. Background

The osteoarthritis (OA) community of clinicians, physicians and scientists have been challenged to get new treatments to market so that people with OA can benefit at the point of care. The Arthritis Foundation and FDA are convening experts to discuss alternative approaches to clinical trials in OA. Workshop objectives will include discussion and identification of promising innovations that could facilitate successful trials in OA, new approaches to recruitment for clinical trials, feasible and clinically meaningful trial endpoints, and approaches for reducing the time and cost of OA trials while maximizing the likelihood of success.

Registration: There is no fee to attend the workshop, but attendees must register in advance. Space is very limited. Persons interested in attending this workshop may request to register by sending their resume and inquiry to AFScience@arthritis.org. The registration deadline is February 2, 2016.

II. Accommodations

An online registration link and a meeting code will be provided through the registration process giving participants a reduced group rate for hotel accommodations, not including applicable taxes. No additional reservations are required. Industry and government attendees are responsible for the cost of their own accommodations. If you need special accommodations due to a disability, please contact Becky Bosworth at bbosworth@arthritis.org at least 7 days in advance.

III. Transcripts

No transcripts will be available from the event, however, the event will be video taped for the purposes of the Arthritis Foundation. Speaker presentation materials, if permitted by the presenter, will be available on the Arthritis Foundation Web site following the workshop.

Dated: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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